



CMS-3301-FN

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**CMS-3301-FN**

**Medicare and Medicaid Programs; Continued Approval of DNV GL - Healthcare (DNV GL) Critical Access Hospital (CAH) Accreditation Program**

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Final notice.

**SUMMARY:** This final notice announces our decision to approve DNV GL - Healthcare (DNV GL)<sup>1</sup> for continued recognition as a national accrediting organization (AO) for critical access hospitals (CAH) that wish to participate in the Medicare or Medicaid programs.

**DATES:** This final notice is effective December 23, 2014 through December 23, 2020.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:**

**I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met. Sections 1820(c)(2)B, 1820(e) and 1861(mm)(1) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities

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<sup>1</sup>Formerly known as Det Norske Veritas Healthcare, Inc. (DNVHC)

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are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F, specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

Generally, to enter into an agreement, a CAH must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart F. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of AOs are set forth at §488.4 and §488.8(d)(3).

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The regulations at §488.8(d)(3) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by us. The DNV GL's current term of approval for their CAH accreditation program expires December 23, 2014.

## **II. Application Approval Process**

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

## **III. Provisions of the Proposed Notice**

On June 27, 2014, we published a proposed notice in the **Federal Register** (79 FR 36521) announcing DNV GL's request for approval of its CAH accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.4 and §488.8, we conducted a review of DNV GL's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of DNV GL's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training,

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monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.

- The comparison of DNV GL's accreditation to our current Medicare CAH conditions of participation (CoPs).

- A documentation review of DNV GL's survey process to:

- ++ Determine the composition of the survey team, surveyor qualifications, and DNV GL's ability to provide continuing surveyor training.

- ++ Compare DNV GL's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate DNV GL's procedures for monitoring CAHs out of compliance with DNV GL's program requirements. The monitoring procedures are used only when DNV GL identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at §488.7(d).

- ++ Assess DNV GL's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish DNV GL's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of staff and other resources.

- ++ Confirm DNV GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV GL's policies with respect to whether surveys are announced or unannounced.

++ Obtain DNV GL's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 27, 2014 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no comments in response to our proposed notice.

#### **IV. Provisions of the Final Notice**

##### **A. Differences Between DNV GL's Standards and Requirements for Accreditation and Medicare's Conditions and Survey requirements:**

We compared DNV GL's CAH requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNV GL's CAH accreditation program application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at §412.25(d), DNV GL revised its standards to address the number of excluded units permitted.
- To meet the requirements at §412.27(c)(2)(vii), DNV GL revised its standards to include the requirement for an inventory of the inpatient's assets in a descriptive fashion and ensured that consistent language is used in the crosswalk and manual.
- To meet the requirements at §412.27(d)(3), DNV GL revised its standards to more

fully address nursing services requirements.

- To meet the requirements §412.27(d)(4), DNV GL revised its standards to address “service objectives” for psychological services.
- To meet the requirements at §412.27(d)(6)(ii), DNV GL revised its standards to address the number of “qualified therapists, support personnel and consultants” needed to provide comprehensive therapeutic activities consistent with each inpatient’s active treatment program.
- To meet the requirements at §412.29(h), DNV GL revised its standards to ensure a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.
- To meet the requirements at §482.12(c)(1)(iv), DNV GL revised its standards related to a doctor of optometry.
- To meet the requirements at §482.12(c)(2), DNV GL revised its standards to address the regulatory language, “patients are admitted to the hospital only on the recommendation of a licensed practitioner.”
- To meet the requirements at §482.13(h)(1), DNV GL revised its standards to more fully address the requirement to inform each patient (or “support person, where appropriate”) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her rights under this section, and ensured consistent language is used in its manual and crosswalk.
- To meet the requirements at §482.21(e)(1), DNV GL revised its standards to ensure that an ongoing quality assurance performance improvement program is “maintained.”

- To meet the requirements at §482.22(c)(5)(i) through (ii), DNV GL revised its standards to ensure that a medical history and physical is conducted, completed, and updated in accordance with “hospital policy.”
- To meet the requirements at §482.25(b)(2)(i), DNV GL revised its crosswalk to address the requirement that all drugs and biologicals must be kept in a secure area, and locked when appropriate.
- To meet the requirements at §482.27(b)(3)(i), DNV GL revised its standards to more fully address the regulatory language related to HIV testing of blood and blood components from a blood donor who tested negative at the time of donation, but tests reactive for evidence of HIV or HCV infection on a later donation , “or who is at increased risk for transmitting HIV or HCV infection.”
- To meet the requirements at §482.30(f), DNV GL revised its crosswalk to address review of professional services.
- To meet the requirements at §482.41(b)(6), DNV GL revised its standards to include a requirement for the proper routine storage and prompt disposal of all trash.
- To meet the requirements at §482.41(b)(7), DNV GL revised its standards to address the evacuation and relocation plan requirement, periodic instruction for employees and a readily available plan in the telephone operator’s position at the security center.
- To meet the requirements at §483.12(a)(8), DNV GL revised its standards to address written advance notice of facility closure.
- To meet the requirements at §483.15(f)(2)(i), DNV GL revised its standards to address this requirement for a qualified therapeutic recreational specialist or an activities professional.

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- To meet the requirements at §483.15(f)(2)(i), DNV GL revised its standards to include standards requiring a qualified therapeutic recreation specialist.
- To meet the requirements at §483.55(a)(1), DNV GL revised its standards to address the requirement that the facility provide or obtain from an outside resource, routine and emergency dental services to meet the needs of each resident.
- To meet the requirements at §485.604(c)(3), DNV GL revised its standards to include the requirement that physician assistants must have been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.
- To meet the requirements at §485.604(b)(3), DNV GL revised its standards and crosswalk to address the requirement that the nurse practitioner must have “been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.”
- To meet the requirements at §485.604(c)(2)(ii), DNV GL revised its standards to more fully address physician assistant supervised clinical practice and classroom instruction program requirements.
- To meet the requirements at §485.606, DNV GL revised its referenced standard and crosswalk to address how DNV GL determines that the appropriate CAH designations and certifications have been made by CMS and/or the state agency.
- To meet the requirements at §485.608, DNV GL revised its standards to include compliance with federal, state and local CAH laws and regulations and to reconcile the inconsistent language between the manual and crosswalk.
- To meet the requirements at §485.608(a), DNV GL revised its standards to address the



requirement that the CAH must be licensed in accordance with federal “regulations.”

- To meet the requirements at §485.608(b), DNV GL revised its standards and crosswalk to address the requirement that all patient services are furnished in accordance with applicable “local” laws, and to address furnishing patient care services in accordance with state and local “regulations.”

- To meet the requirements at §485.608(c), DNV GL revised its standards to address the requirement that the CAH is licensed in accordance with applicable federal, state, and local “regulations.”

- To meet the requirements at §485.608(d), DNV GL revised its standards to address the requirement that staff of the CAH are “licensed, certified, or registered in accordance with applicable federal, state, and local regulations.”

- To meet the requirements at §485.612, DNV GL revised its standards to ensure the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

- To meet the requirements at §485.616(a), DNV GL revised its standards and crosswalk to address agreements with network hospitals.

- To meet the requirements at §485.616(b), DNV GL revised its standards and crosswalk to address agreements for credentialing and quality assurance.

- To meet the requirements at §485.616(c) through (c)(1)(ii), DNV GL revised its standards to address agreements for credentialing and privileging of telemedicine physicians and practitioners.

- To meet the requirements at §485.616(c)(2)(iv), DNV GL updated their Medicare

cross-walk to include standards to address when telemedicine services are provided to the CAH's patients through an agreement with a distant site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions of the distant site hospital.

- To meet the requirements at §485.616(c)(3), DNV GL revised its standards to address the governing body of the CAH must ensure that telemedicine services are furnished in accordance with §485.635(c)(4)(ii) and to ensure consistent language in its crosswalk.

- To meet the requirements at §485.618(c), DNV GL revised its standards to address the requirement that the facility provide blood and blood products, either directly or under arrangement.

- To meet the requirements at §485.618(c)(1), DNV GL revised its standards to address the requirement that the facility provide services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24- hour a day basis.

- To meet the requirements at §485.618(c)(2), DNV GL revised its standards and crosswalk to address blood storage facilities.

- To meet the requirements at §485.618(d)(1), DNV GL revised its standards to address personnel requirements and to ensure consistent language in its crosswalk.

- To meet the requirements at §485.623, DNV GL revised its standards to address physical plant and environment and to ensure consistent language in its crosswalk.

- To meet the requirements at §485.631(b)(1)(ii), DNV GL revised its standards to address written policies governing services the CAH furnishes.

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- To meet the requirements at §485.631(b)(1)(iii), DNV GL revised its standards to address the requirement for providing medical orders.
- To meet the requirements at §485.631(b)(2), DNV GL revised its standards to address the requirement for providing medical care services.
- To meet the requirements at §485.631(c)(1)(i), DNV GL revised its standards to address other CAH non-clinical written policies.
- To meet the requirements at §485.635(a)(3)(ii), DNV GL revised its standards to address the requirement for emergency medical services policies and procedures.
- To meet the requirements at §485.635(a)(3)(iii), DNV GL revised its standards to address “the maintenance of health care records.”
- To meet the requirements at §485.635(a)(3)(iv), DNV GL revised its standards to address the requirement that current and accurate records are kept of the receipt and disposition of all scheduled drugs.
- To meet the requirements at §485.635(b)(1)(ii), DNV GL revised its standards to clarify how their surveyors determine that a CAH furnishes acute care inpatient services when no inpatients are present at the time of the survey.
- To meet the requirements at §485.635(d)(1), DNV GL revised its standards to clarify under what authority nursing services may be provided or supervised by a Physician Assistant (PA) where permitted by state law.
- To meet the requirements at §485.635(d)(4), DNV GL revised its standards and crosswalk to fully address the requirement that a nursing care plan must be developed and kept current for each patient.

- To meet the requirements at §485.638(a)(4), DNV GL revised its standards to more fully address the requirement that the CAH maintains a medical record for each patient receiving health care services.

- To meet the requirements at §485.638(a)(4)(iii), DNV GL revised its standards to fully address the requirement that the medical record contains “reports of treatments and medications.”

- To meet the requirements at §485.639(a), DNV GL revised its standards to fully address the requirement related to designation of qualified practitioners allowed to perform surgery “in accordance with approved policies and procedures, and with state scope of practice laws.”

- To meet the requirements at §485.639(b)(2) and (b)(3), DNV GL revised its standards to address the requirement to specify a “qualified” practitioner examine each patient before surgery to evaluate the risk of anesthesia.

- To meet the requirements at §485.641(b)(5)(i), DNV GL revised its standards to fully address the requirement that the CAH consider the findings of the evaluations, “including any findings or recommendations of the Quality Improvement Organization (QIO),” and takes corrective action if necessary.

- To meet the requirements at §485.645, DNV GL revised its standards to explain how it would determine that we have granted approval for the CAH to provide and be paid for post-hospital SNF level care as specified in 42 CFR 409.30.

- To meet the requirements §488.28(a) and section 2728B of the State Operations Manual (SOM), DNV GL amended its policies to ensure that the accepted PoCs contains the

elements comparable to those specified in the SOM, section 2728B.

- To meet the requirements at §488.6, DNV GL provided a written plan to address the components of the CAH application for Distinct Part Units (DPUs) and swing beds, and to ensure that the surveys consistently document evaluation of the CAH's DPUs and swing beds, as applicable.

- To meet the requirements at §488.8(a)(2)(iv), DNV GL developed an action plan designed to: strengthen DNV GL surveyor documentation skills; consistently develop more detailed, quantifiable deficiency statements that contain all evidence collected by the survey team; and support the determination of the manner and degree of non-compliance and the appropriate level of citation.

- To meet the requirements at §489.13(b), DNV GL revised its policy for determining the effective date of accreditation for an initial and re-accreditation survey.

#### B. Term of Approval

Based on our review and observations described in section IV of this final notice, we have determined that DNV GL's CAH accreditation program requirements meet or exceed our requirements. Therefore, we approve DNV GL as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 23, 2014 through December 23, 2020.

#### **V. Collection of Information Requirements**

This document does not impose information collection, recordkeeping requirements or third party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C.

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Dated: November 13, 2014.

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**Marilyn Tavenner,**

Administrator,

Centers for Medicare & Medicaid Services.

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